DOCUMENT-IDENTIFIER: US 5645347 A
TITLE: Mixing apparatus with mixing rod supporting lid

---------- KWIC ---------

ABPL:
The invention relates to a mixing apparatus comprising a **mixing bowl** (10) and a
lid (70) for vacuum-sealing the **mixing bowl** (10), which lid is provided with a
passage (84) for a mixing rod. The lid (70) is relatively rigid in the axial
direction of the **mixing bowl** (10), whereas at least the portion of the lid (70)
which surrounds the passage (84) is radially movable. (FIG. 3.)

BSPR:
The invention relates to an apparatus for stirring substances and for mixing a
compound or a mixture of substances comprising at least two components. In
particular, the invention relates to an apparatus for mixing **bone** cement and
filling it into an applicator.

BSPR:
Further, specific problems arise in the processing and mixing of **bone** cement
and when filling the same into the vessel from which the **bone**

cement is later
applied.

BSPR:
The **bone** cement is usually made of cold-curing two-component resins which
anchor the components of artificial joints into the bony bed. The **bone** cement
hardens as soon as it has been applied. Due to its plastic properties, it
anchors the components of the prosthesis into the bony bed by interlocking.
Polymethylmethacrylates (PMMA) have been used as **bone** cement for several years
now. They comprise a powdery bead polymer which is superficially dissolved in
a liquid monomer and is then embedded by the polymerisation of said liquid
monomer. In the mixing phase, the monomer surrounds the usually globular
polymer powder. This firstly leads to a suspension of the globules in which a
considerable amount of air bubbles are entrapped. The process of polymerisation occurs exothermically. In addition to the entrapped air
bubbles, when the polymer globules are surrounded by the monomer, so-called
"lee phenomena" regularly appear; this means sites where the polymer globules
have not been sufficiently wetted. In addition, the monomeric liquid
evaporates during the process of exothermal polymerisation which

leads to the
fact that in the end the hardened **bone** cement is riddled with bubbles of
various ethiology and genesis.

BSPR:
As a rule, the polymer powder is added to the monomer and then mixed in a bowl
using a spatula. In the processing phase which follows the mixing phase, the
bone cement is applied to the bony bed either manually, which is usually the
case, or sometimes with a syringe. To date there are hardly any publications
that deal with the mixing phase and bloating phase of the **bone** cement and with
the artefact-free insertion thereof into the syringe system.

BSPR:
The further processing of the **bone** cement stirred in the **mixing bowl** in the
above-mentioned fashion depends on its viscosity. **Bone** cement of a very low
viscosity can be poured from the bowl into the cartridge of the **bone** cement
syringe; the problem, however, is that the stream of **bone** cement flowing into
the syringe can be very easily diverted, for instance via electrostatic
charging, so that the walls of the cartridge and the opening thereof are almost
always covered with **bone** cement. Highly viscous **bone** cement

cannot be poured
at all. It has to be removed and kneaded by hand in order to press out the
largest of the air enclosures. The **bone** cement is then rolled into a sausage-shaped mass which can be inserted into the cartridge. When manually
processing the cement, not only does one have to wait until the **bone** cement no
longer sticks to the surgical gloves, but the cement mixture also remains
unprocessed in the most important stage of the bloating or swelling phase and
the pre-polymerisation phase that follows.

BSPR:
A further object of the invention is to provide a device for mixing **bone** cement
and filling it into an applicator with which apparatus **bone** cement consisting
of several components can easily, rapidly, without bubbles and without being
touched by the surgeon be mixed and filled into an applicator from which the
bone cement is to be applied to the bony bed.

BSPR:
According to the invention, the substances to be mixed, preferably a curable
two-component system such as a mixture of polymer powder and monomer, are
pushed through an opening or taper out of a **mixing bowl** into the applicator

after having been mixed in said **mixing bowl**. This process is called "extrusion
mixing".

BSPR:
The **mixing bowl** or mixing vessel is preferably cylindrical with one closed and
one open end. The applicator vessel in which the compound is further processed
once it has been intermixed or blended, is preferably cylindrical, too, and has
one open end. The other end of the applicator vessel or the second vessel can
be closed by means of a cap or plunger. The outer perimeter of the second
vessel is provided with a sealing means, preferably at the open end thereof,
the sealing means preferably comprising several flexible discs or lamellae.

BSPR:
When applying the above principle to mixing **bone** cement and filling it into an
applicator, the monomer is firstly placed into a **mixing bowl** or cup whereupon
the polymer powder is added to the formulation and is mixed and stirred under
vacuum, as will be explained in detail. Instead of removing all of the cement
paste with the spatula, or pouring it out if the cement has a low viscosity, as
in conventional processes, the cartridge-shaped applicator with its

mounted
sealing means is inserted through the opening of the **mixing bowl**. If the
sealing means is provided as a cylindrical member with a central, tubular
opening and several disc-shaped lamellae, said means can be mounted to any kind
of commercially available cartridge by means of adapters, preferably small
rings, and can be used in combination with these cartridges. The cylindrical
vessel described in EP-A1-170 120 is the one preferably used as the applicator
or cartridge. By pushing in the cartridge and the sealing means coupled
thereto, the cement which has been pre-mixed with the spatula is forced into
the cartridge through the central opening of the sealing means. The diameter
of the opening can be either the same or smaller than that of the cartridge.
The extruding effect leads to a more thorough mixing of the **bone** cement, and it
proceeds from the **mixing bowl** into the cartridge without having been touched by
the surgeon's hands. Furthermore, the flowing process presses out large air
bubbles.

BSPR:
According to the invention, instead of using a conventional spatula to premix

the cement, a mixing apparatus is used which preferably comprises a round rod
advantageously coated with teflon. The round rod has the advantage that it
does not rupture the mixture, but promotes the blending thereof by means of a
laminar flow of the layers of the mixture. Furthermore, when mixing the **bone**
cement and removing the rod, almost no cement sticks to the teflon-coated round
rod.

BSPR:
In order to avoid air enclosures, the mixing of the components, for example the
components of the **bone** cement, is carried out under vacuum. For this, the
mixing vessel preferably has a surface ground upper rim onto which a lid or cap
is mounted. The mixing vessel can be sealingly connected with the lid by means
of a sealing ring covered with vacuum grease or by means of a silicon coating.
The lid can also be connected to the mixing vessel in a vacuum-tight manner by
means of an easily removable flanged joint. The lid has a connecting means for
a tube feed to which a vacuum pump is attached.

BSPR:
According to the invention, the lid of the **mixing bowl** is formed thus that it

essentially stays in shape and is not, for instance, dragged into the **mixing bowl** when under partial vacuum, i.e. when the **mixing bowl** is being evacuated.
At the same time said lid is flexible enough for the mixing rod, which is inserted through a feed-through or passage in the lid in a vacuum-tight manner, to be movable or mobile in the radial direction of the **mixing bowl** so that it is possible to carry out a stirring movement with the mixing rod in the evacuated **mixing bowl**. The lid is preferably flexible enough to allow the mixing rod to be led along and parallel to the entire inner wall of the **mixing bowl,** but at least along its bottom inner rim. In the axial direction, however, the lid must be stiff enough to prevent it from being crushed or pulled into the **mixing bowl** during evacuation.

BSPR:
The lid preferably has a firm rim which is placed onto the rim of the mixing vessel, and a feed-through or passage for the round rod used in the mixing process. The sealed feed-through for the round rod is preferably arranged within an inner portion of the lid, said inner portion being made of flexible material or flexibly shaped in another manner, and the lid being connected in a

vacuum-tight fashion, preferably integrally, to the firm rim. The inner
portion of the lid can be tent-like and can have at its upper end the feed-through or passage which is shaped as an annular guiding means and is
preferably made of rubber or silicon, through which the round rod is fed and
which holds said round rod in a vacuum-tight manner. As the inner portion of
the lid is flexible, the round rod can be moved or is mobile in a radial
direction within the mixing vessel and can be guided along the inner wall of
the mixing vessel so that none of the components to be mixed, for instance no
bone cement powder, remains on the inner wall untouched. This is of
extraordinary significance for obtaining thorough mixing. In this embodiment,
the material the lid is made of must be stiff enough to withstand completely
collapsing when under partial vacuum.

BSPR:
In a further preferred embodiment, the lid is integrally shaped in the form of
bellows which taper as they go up, i.e. away from the **mixing bowl**. The
bellow-shaped lid preferably consists of several, preferably three to five,
cylindrical portions which essentially extend in the axial direction. The

diameter of the portions decreases from portion to portion, and they are each
connected by means of an arched transition piece. The transition pieces can be
less thick than the axial portions. The bottommost portion of the lid can be
thicker and thus stiffer than the other portions and can form the rim located
on the upper rim of the **mixing bowl**. The rim of the lid preferably encompasses
the rim of the **mixing bowl** in the form of an undercut and in such a manner that
the lid is mounted on the **mixing bowl** in a vacuum-tight and essentially rigid,
non-displacable manner. The inner diameter of the uppermost portion of the lid
forms the feed-through for the mixing rod.

BSPR:
By mixing the **bone** cement under vacuum, the number of bubbles in the cement can
be diminished even further and the mixture can be stirred without almost no
bubble formation.

BSPR:
Experiments have shown that tall mixing vessels enable a much quicker and more
homogenous mixing of the cement paste than wide, shallow **mixing bowls** or dishes
which exhibit dead corners. The inner bottom of the mixing vessel is

preferably spherical or concave. When the cartridge is pressed in, the first,
flexible lamella of the sealing means adapts itself to the shape of the bottom
of the **mixing bowl** in such a manner that no substance remains in the **mixing**
bowl. It is of particular advantage if the bottom of the **mixing bowl** is
flexible, too, so that the complete adaption of the two forms is assured.

BSPR:
The formation of dead spaces at the upper edge of the cement paste during the
flowing process can be avoided if the foremost lamella of the sealing means is
also slightly bent or concave so that the cement paste is forced radially from
the outer wall of the **mixing bowl** to its centre.

BSPR:
Furthermore, during the mixing phase it is also possible to apply a vacuum and
to evacuate air from the **mixing bowl** by applying pressure and closing the
central opening or the end of the cartridge while mechanically compressing the
cement at the same time. The result is that the majority of the small air
bubbles, too, can be removed from the cement as early as in the mixing stage.

BSPR:
When filling the cement into the cartridge it is important that the end facing
away from the **mixing bowl** is not closed or, if the cartridge has a cap, that
said cap is only loosely mounted to allow the air which is pushed out in front
of the cement to escape from the cartridge.

BSPR:
In the system described above, which is called the "half closed system", the
second vessel can be a cartridge as used in the **bone** cement syringe according
to EP-A1-170 120 or in similar syringes. In this system, the cement does not
have to be touched by the surgeon's or scrub-nurse's hands or surgical gloves
prior to its application, which is of great advantage. On the one hand it is a
known fact that the monomer can easily penetrate the rubber gloves of the
operating team, and more and more allergies to the plastic they are made of
have recently become known; on the other hand, the contact-free procedure leads
to a considerable reduction in the number of flaws in the cement, and it
proceeds more quickly and at an earlier stage into the **bone** cement pistol for
precompression because one does not have to wait for it to set.

BSPR:
The first vessel (**mixing bowl**) and the second vessel (applicator) are
preferably made of the same material. They can be made of plastic, preferably
a thermoplastic material such as a polyolefin. The use of poly(4-methyl-1-pentene) or TPX.RTM. is particularly preferred. It is also
possible to use polycarbonate.

DRPR:
In the following the invention will be explained in greater depth using
examples relating to mixing **bone** cement and filling it into an applicator, and
using illustrations. The figures show:

DRPR:
FIG. 1: an apparatus for mixing substances and filling the blended substances,
such as **bone** cement, into an applicator.

DEPR:
The apparatus according to FIG. 1 comprises a tall, circular, cylindrical
mixing bowl 10 having a round inner bottom 12 and a flat base 14.

DEPR:
The applicator 20 is formed as a syringe cartridge and has a corrugated
gripping surface 22 and a conical front end 24 serving as a mouth piece for the

application. A closure cap 26 is attached to this end by means of a bayonet
closure 25 having a rising thread, said cap sitting close to a rib 27 on the
applicator which serves as a stopper. On the other (during application rear)
end of the vessel 20, a sealing means 30 is fastened by means of an adapter 28.
The tubular body 32 of the sealing means 30 has in its interior a central
opening and five flexible lamallae 34a-e at its perimeter. The sealing means
30 is made of teflon and the diameter of the lamallae gradually increases
starting from the foremost lamella 34e which faces the bottom of the **mixing**
bowl 10 and has the smallest diameter.

DEPR:
When mixing the **bone** cement, first the monomer and then the polymer powder is
placed into the **mixing bowl** 10 and mixed; this will be explained in greater
detail on the basis of FIGS. 2 to 4. Then the applicator 20 with its mounted
sealing means 30, as shown in FIG. 1, is pushed from above into the **mixing bowl**
10 the top of which is open. When doing this the lamellae then adapt
themselves to the shape of the rounded inner bottom 12 of the **mixing bowl** 10
and all of the **bone** cement is forced through the central opening of

the sealing
means 30 into the vessel 20. The lamellae 34 are designed in such a way that
the air above the **bone** cement and/or the gases which escape during
polymerisation can escape past the lamellae 34, but that, if at all, the **bone**
cement can only pass by a certain number of the lamellae. The graduated
diameter of the lamellae 34 assures that the **bone** cement cannot pass through
all the lamellae even if one allows for a certain process tolerance range.

DEPR:
Once all the **bone** cement has been filled into the vessel 20 in this way, the
adapter 28 with the sealing means 30 is removed from the vessel 20 and the
vessel 20 is mounted onto a **bone** cement syringe such as the **bone** cement pistol
according to EP-A1-170 120. Thus the applicator 20 serves directly as a
cartridge for the application of the **bone** cement.

DEPR:
The **mixing bowl** 10 according to FIG. 2 basically corresponds to the **mixing bowl**
according to FIG. 1 and has a concave inner bottom 12 and a surface ground
upper rim 16. In order to enable stirring and mixing under vacuum, the **mixing**

bowl 10 according to FIG. 2 comprises a vacuum lid 50, the firm rim 52 of which
lies on the surface ground rim 16 of the **mixing bowl** 10. A silicon layer can
be used to sealingly connect the two surfaces of the rim 16 and 52 which
contact, but it is also possible to provide a sealing ring in a groove of the
rim 16. The outer portion of the rim 52 of the lid 50 has a nose 54 which
overlaps the rim 16 and prevents the lid 50 from being displaced relative to
the rim 16 of the **mixing bowl** 10.

DEPR:
The apparatus according to FIG. 2 is used to stir or premix the raw mixture of
monomer and polymer powder in the **mixing bowl** 10 under vacuum in about the
first 30 seconds of the mixing phase. As the inner portion 60 of the lid 50 is
flexible, the round rod 64 is radially movable within the **mixing bowl** 10 and
can also be guided along the inner side wall of the **mixing bowl** 10. For this
purpose, it is important that the lid 50 does not protrude radially or inwardly
over the inner wall of the **mixing bowl** 10. The round rod is used in order to
prevent the cement from sticking to the rod during stirring and when later
removing the rod and to prevent the mixture from rupturing, but to

produce a
laminar flow of the individual layers of the mixture, by means of which the
process of blending is promoted.

DEPR:
Once the stirring and mixing phase has been completed, the round rod 64 is
removed and the lid 50 is detached from the **mixing bowl** 10. The **bone** cement,
as explained in connection with FIG. 1, can then be extruded into the
applicator.

DEPR:
FIG. 3 shows a further embodiment of a vacuum lid or cap 70 for the **mixing bowl**
10 in a cross sectional view, part of the **mixing bowl** 10 being shown in view.

DEPR:
The **mixing bowl** 10 according to FIG. 3 corresponds to the **mixing bowl** 10
according to FIG. 2, with FIG. 3 showing the provision of a corrugated gripping
surface 14.

DEPR:
The vacuum lid 70 is integral and its shape comparable to that of taper-shaped
bellows. The lid 70 consists of several connected portions, the diameter of

which gradually decreases. The bottommost portion 72 is thicker than the other
portions and serves as a rim which is mounted on the rim 16 of the **mixing bowl**
in a vacuum-tight manner. For this purpose the portion 72 exhibits a nose 74
which firmly encompasses the rim 16 of the **mixing bowl** in the form of an
undercut. Due to the elasticity of the material, the rim 72 can easily be
pushed outwards to mount it on the **mixing bowl** 10.

DEPR:
In all, the lid 70 should be elastic enough to let the uppermost portion 80d be
radially moved to such an extent that the mixing rod, which is inserted through
the feedthrough 84, lies parallel to the inner wall surface of the **mixing bowl**
10 and can be moved along this surface.

DEPR:
The vacuum lid 90 according to FIG. 4 comprises a solid bottommost portion 92
which serves as a rim at the same time. The projection 93 of said portion
encompasses the upper rim of the **mixing bowl,** and said portions connects the
vacuum lid 90 to the **mixing bowl** (only outlined in FIG. 4) in a vacuum-tight
manner.

DEPR:
The bottommost portion 92 tapers as it goes up to the next portion 94a which
essentially extends in the axial direction, as is the case in portion 92. The
further portions 94b and 94c are of essentially the same thickness as portion
94a and are slightly conical and inclined in an inward direction. Loop-shaped
transition pieces 96a, 96b and 96c are provided between each of the portions of
the vacuum lid 90 and have a double U shape and are of the same thickness as
the middle portions of the vacuum lid 90. The uppermost transition piece 96c
thickens towards the end and merges into the equally thickened uppermost
portion 94d of the vacuum lid 90, the inner perimeter of which forms the
holding means or feed-through for a round mixing rod (not shown in FIG. 4).
The upper surface of the thickened portion of the transition piece 96c is
inclined at an angle of about 30.degree. to the axial direction, and the lower
surface thereof is inclined at an angle of about 45.degree.. This is of
special advantage for the flexibility of the feed-through for the mixing rod.
On the whole the vacuum lid 90 and its meander-shaped cross section are
extraodinarily flexible which means that the mixing rod can still be easily

moved to stir the **bone** cement when under vacuum. As regards the flexibility of
the vacuum lid 90, its extended, loop-shaped cross section together with the
properties of material it is made of are especially advantageous. The material
used for the vacuum lid 90 is preferably Hytrel.RTM. or Santoprene.RTM..

DEPR:
The invention is not limited to the above examples which relate to mixing **bone**
cement and filling it into an applicator, but can be generally used to blend a
mixture consisting of at least two components and to fill the blended mixture
into a vessel or container. The aforementioned examples of the apparatus
according to the invention can therefore be generally applied in stirring and
mixing substances and filling them into a vessel.

CLPR:
1. A mixing apparatus comprising a **mixing bowl** having an interior and having a
generally vertical, longitudinal axis and a lid for sealing the **mixing bowl** in
a vacuum-tight manner, said lid comprising a passage therethrough receiving a
mixing rod, wherein the lid is relatively rigid in the axial direction of the
mixing bowl against a vacuum established within the **mixing bowl**

while the lid
is flexible enough for transverse movement of at least a portion of the mixing
rod in a radial direction of the **mixing bowl** such that a stirring movement can
be carried out by means of the mixing rod in the interior of the **mixing bowl,**
said mixing apparatus further comprising a feed-through connector disposed in
said lid for connecting the interior of the **mixing bowl** to a vacuum means.

CLPR:
2. The mixing apparatus according to claim 1, wherein the lid comprises a firm
rim and an inner portion which is flexible in the radial direction of the
mixing bowl and comprises the passage for the mixing rod.

CLPR:
9. The mixing apparatus according to claim 1, wherein the **mixing bowl** is
cylindrical and has an inner bottom which is concave or rounded.

CLPR:
10. The mixing apparatus according to claim 1 provided in a mixing apparatus
kit, wherein the mixing apparatus **kit** further comprises an applicator having a
cross section which is smaller than that of the **mixing bowl** and which can be
moved in the **mixing bowl** relative to the same, the applicator

having an outer
perimeter and further comprising sealing means at the outer perimeter, which
sealing means seals off a space between the inner perimeter of the **mixing bowl**
and the outer perimeter of the applicator for substances to be mixed when the
mixing bowl and the applicator are moved relative to one another.

CLPR:
11. The mixing apparatus according to claim 1, wherein the lid is flexible
enough during a stirring movement of the mixing rod to allow the mixing rod to
be led along an entire surface of an inner bottom wall of the **mixing bowl**.

CLPR:
14. The mixing apparatus according to claim 1, provided in a mixing apparatus
kit, wherein the mixing apparatus **kit** further comprises:

CLPR:
16. A mixing apparatus **kit** comprising:

CLPV:
an applicator for receiving contents of the **mixing bowl,** the applicator being
attachable to the **mixing bowl** following the removal of the mixing rod and the
lid from the **mixing bowl**.

CLPV:
a **mixing bowl** having a generally vertical, longitudinal axis, a bottom wall,
and a side wall defining a top opening and an interior area;

CLPV:
a lid sealed against the top opening for sealing the **mixing bowl** in a
vacuum-tight manner, the lid having a passage therethrough, and wherein the lid
is relatively rigid along a direction of the longitudinal axis of the **mixing**
bowl against a vacuum established within the **mixing bowl**;

CLPV:
a mixing rod maintained by the passage for stirring contents within the
interior of the **mixing bowl,** wherein the lid is flexible enough for transverse
movement of at least a portion of the mixing rod in a radial direction of the
mixing bowl such that the mixing rod can be led along an entire surface of the
bottom wall; and

CLPV:
a feed-through connector disposed in said lid for connecting the interior of
the **mixing bowl** to a vacuum means.

CLPV:
a **mixing bowl** having a generally vertical, longitudinal axis, a

bottom wall,
and a side wall defining a top opening and an interior area;

CLPV:
a lid sealed against the top opening for sealing the **mixing bowl** in a
vacuum-tight manner, the lid having a passage there through, and wherein the
lid is relatively rigid along a direction of the longitudinal axis of the
mixing bowl against a vacuum established within the **mixing bowl,** the lid
further having a feed-through connector disposed therein for connecting the
interior of the **mixing bowl** to a vacuum means;

CLPV:
a mixing rod maintained by the passage for stirring contents within the
interior of the **mixing bowl,** wherein the lid is flexible enough for transverse
movement of at least a portion of the mixing rod in a radial direction of the
mixing bowl such that the mixing rod can be led along an entire of the bottom
wall; and

CLPV:
an applicator for receiving contents of the **mixing bowl,** the applicator being
adapted to be attached to the **mixing bowl** following the removal of the mixing

rod and the lid.